

App. Serial No. 09/943,286
Filed: August 30, 2001

REMARKS

Applicant acknowledges receipt of the Communication mailed November 13, 2002 (Paper No. 7).

Claims 56-104, 107 and 111-115 have been canceled, Claim 105 has been amended, and Claim 116 has been added by this Second Preliminary Amendment. The last step of method Claim 105 was amended to define more precisely the ability of the recited detection system to yield positive and negative results, and to specify clear interpretations for each of these results. Support for these amendments can be found in the Specification, for example, beginning on page 51 at line 13 and extending through Example 7. Support for New Claim 116 can be found in the Specification on page 52 at line 25-26.

Claims 105-106, 108-110 and 116 will be pending after entry of the present Amendment. A clean set of these pending claims is attached.

Entry of this Amendment is respectfully requested.

RESPONSE TO RESTRICTION REQUIREMENT

The Examiner has required that Applicant elect for initial prosecution an invention defined by one of the following five groups of claims:

- I. **Claims 1-28**, drawn to a method for quantifying an analyte polynucleotide in a sample;
- II. **Claim 29-40**, drawn to a method for relating pre-amplification amounts of analyte polynucleotide and post-amplification amounts of analyte amplicon;
- III. **Claims 41-49**, drawn to a method of determining whether a biological sample contains an analyte polynucleotide;
- IV. **Claim 50**, drawn to a method for determining whether an analyte polynucleotide is present in a test sample in an amount greater or less than a predetermined value; and

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V. Claims 51-55, drawn to a kit for performing an amplification reaction.

Claims 1-55 were canceled by a Preliminary Amendment that was filed with the present Continuation Application on August 30, 2001. In a brief telephone discussion with the Examiner on November 22, 2002 it was learned that the Preliminary Amendment was inadvertently not entered prior to issuance of the Restriction Requirement.

In view of the amendments made herein, Applicant believes that it will be unnecessary for the Examiner to reissue a new Restriction Requirement preliminary to examination on the merits.

Conclusion:

Applicant requests entry of the Preliminary Amendment filed August 30, 2001, as well as the amendments made herein. Following these entries the application is believed in condition for examination on the merits. Such examination is respectfully requested. Should there be any remaining questions concerning the application, the Examiner is requested to contact the undersigned at the telephone number appearing below.

Dated: Jan. 13, 2003

Respectfully submitted,
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Clean Version of the Pending Claims

105. (Amended) A method of determining whether an analyte polynucleotide is present in a test sample in an amount greater or less than a pre-determined value, comprising the steps of:

obtaining a test sample to be analyzed for the presence of said analyte polynucleotide, said analyte polynucleotide being selected from the group consisting of a viral polynucleotide, a bacterial polynucleotide, a fungal polynucleotide, a protozoan polynucleotide, and a human polynucleotide;

combining said test sample with an amount of a pseudo target;

co-amplifying in a polynucleotide amplification reaction the pseudo target and any analyte polynucleotide contained in said test sample to produce amplification products that include a pseudo target amplicon and an analyte amplicon, wherein said analyte amplicon is present in an amount that is dose-dependent on the amount of said analyte polynucleotide present in said test sample; and

quantitatively detecting said analyte amplicon using a detection system calibrated to indicate a positive result upon detecting an amount of analyte amplicon arising from co-amplification of said amount of said pseudo target and an amount of analyte polynucleotide equal to or greater than said pre-determined value, wherein a positive result indicates that said analyte polynucleotide is present in said test sample in an amount equal to or greater than said pre-determined value, and wherein a negative result indicates that said analyte polynucleotide is present in said test sample in an amount less than said pre-determined value.

106. The method of Claim 105, further comprising a step for detecting the pseudo target amplicon produced in the co-amplifying step.

108. The method of Claim 105, wherein said detection system comprises luminometry.

109. The method of Claim 105, wherein said analyte polynucleotide is a viral polynucleotide.

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110. The method of Claim 109, wherein said viral polynucleotide is selected from the group consisting of an HIV-1 polynucleotide, an HIV-2 polynucleotide, an HBV polynucleotide, and an HCV polynucleotide.

B2 116. (New) The method of Claim 105, wherein said detection system is selected from the group consisting of a chemiluminescent detection system, a fluorescent detection system, an optical detection system, and an electro-chemical detection system.

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January 13, 2003